K082465

510(K) SUMMARY

EarlySense Ltd.

MAR 2 5 2009

EverOn System

7.1.1 Applicant's Name:

EarlySense Ltd.
12 Tzvi st.
Ramat Gan 52504, Israel
Tel: +972-3-7522330
Fax: +972-3-7522340

7.1.2 Contact Person:

Dalia Argaman

7.1.3 Date Prepared:

March, 2009

7.1.4 Trade Name:

EverOn System

7.1.5 Classification Name:

Breathing frequency monitor (868.2375)

7.1.6 Classification:

Class II; Product Code- BZQ

7.1.7 Predicate Devices

The ES-16 System, cleared under K070375.

7.1.8 Device Description:

The modified EarlySense™ EverOn System is designed for continuous and contact-less monitoring of respiration and heart rates. The system automatically starts measuring whenever the patient is in bed under resting or sleeping conditions. The EverOn enables the user to define upper and lower thresholds so an alert notification (audible and visible) is given to the user, if either heart rate or respiration rate exceed the thresholds set by the user. The EverOn also detects patient movement levels and provides patient out-of-bed (Bed Exit) notification to the user.

The EverOn System consists of the following main components:

- A Sensing Unit placed under the mattress or mattress pad.
- A Control Unit (Bedside Unit).
- Proprietary recording and data analysis software

The under mattress Sensing Unit includes a piezoelectric sensor, which converts mechanical movements into an electric signal. The Control Unit receives the electric signals, processes them and finally calculates, logs, displays the patient's parameters, and generates alerts as per set thresholds. when needed.

7.1.9 Intended Use:

The EverOn (modified EarlySense™ ES-16) system is intended for continuous measurement of respiration rate and heart rate, in an automatic contact-less manner, at home, hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EverOn has been studied in children (weight ≥10 Kg) and adults (weight ≤111 Kg) during sleep and resting condition.

7.1.10 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the modified ES-16 System complies with voluntary standards such as IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, AAMI / ISO 14971-1.

7.1.12 Performance Data & Substantial Equivalence

The EverOn System is substantially equivalent in all aspects, e.g., technological characteristics (i.e., Piezo-electric sensing), mode of operation (contact-less monitoring), performance characteristics (accuracy), intended use, etc., to the ES-16 System cleared under K070375.

The modifications involve the following main changes:

Software and User Interface

- An option was added enabling to notify the user (alert) when certain heart rate and respiration rate thresholds, pre-defined by the user, have been crossed.
- An option of bed exit notice was added. The system detects, records and reports body motion level and alerts upon bed exit.
- The user's interface was improved to include a clearer, more interactive and user friendly interface to enhance presentation of information to the user and to allow the user to insert event into the system log-files.

Hardware

The design of the Control Unit has been changed as follows:

- The external design of the bedside Control Unit was changed to include a larger control unit that allows the presentation of larger icons and graphs, enabling a clearer and more convenient user interface.
- Control buttons and LEDs were added to the Control Unit, allowing for more convenient and intuitive user interaction.
- A connector (relay) was added to allow for interface with existing nurse call systems.

The modified System was subjected to the following testing:

- Electrical and electromagnetic testing
- Mechanical vibration and shock resistance testing
- Operational Environmental testing
- Software verification and validation
- Bench testing of alerting features
- Performance testing demonstrating the accuracy of the system (bench and clinical data)

Based on the design verification and validation processes, performed as a result of risk analysis assessment, EarlySense Ltd. believes that the EverOn System, is substantially equivalent to the cleared ES-16, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dalia Argaman
Vice President, Clinical and Regulatory Affairs
EarlySense Limited
12 Zvi Street
Ramat Gan 52522
ISRAEL

MAR 2 5 2009

Re: K082465
Trade/Device Name: EverOn System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: February 5, 2009
Received: February 10, 2009

Dear Ms. Argaman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_____

Device Name: EverOn System

Indications for Use:

The EverOn (modified EarlySense™ ES-16) system is intended for continuous measurement of respiration rate and heart rate, in an automatic contact-less manner, at home, hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EverOn has been studied in children (weight ≥10 Kg) and adults (weight ≤111 Kg) during sleep and resting condition.

Prescription Use __√__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ision Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: k082465